



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/517,863

06/06/2005

Kevin R. Stone

082066-0172 CROL-0155

9012

48329 7590 03/18/2008

FOLEY & LARDNER LLP
111 HUNTINGTON AVENUE
26TH FLOOR
BOSTON, MA 02199-7610

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,863	Applicant(s) STONE, KEVIN R.	
	Examiner SUZETTE J. GHERBI	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29-32, 36-38, 41-56 and 61-87 is/are rejected.
- 7) ☒ Claim(s) 28, 33-35, 39-42 and 57-60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 recites the limitation "the fibers". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 16-18, 25-28, 32, 43, 45-46, 48, 50-54, 63-67, 69-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone **5116374**.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Stone discloses the invention as currently claimed comprising:

A method of making a prosthetic device for implantation into a subject, comprising the steps of: (a) obtaining a substantially immunologically-compatible matrix material, wherein the matrix material is substantially lacking a plurality of first surface carbohydrate moieties; (b) fabricating the matrix material to form a device, wherein the device is adapted to have an in vivo an outer surface contour substantially the same as that of a region disposed between and connecting two of the subject's bones.

... wherein the device is formed as a prosthetic device selected from the group consisting of a meniscal augmentation device, a device formed as a sheet sized to be inserted within the segmental defect of a meniscus, a prosthetic intervertebral disc, a prosthetic ligament and a prosthetic articular cartilage device.;

...immunologically-compatible matrix material in step (a) comprises: (i) removing at least a portion of a soft tissue from a nonhuman animal to provide a matrix material; (ii) washing the matrix material in water and alcohol; (iii)

subjecting the matrix material to a cellular disruption treatment; and (iv)
digesting the matrix material with a glycosidase, whereby the matrix material
is substantially non-immunogenic;
...wherein the glycosidase is a galactosidase.

....wherein the galactosidase is an .alpha.-galactosidase.; and including all of the claim
limitations as set fourth in claims 68-87. Please see cols 4-14 including claims of
patent 5,116,374.

Claims 1, 11-14, 19-20, 32, rejected under 35 U.S.C. 102(e) as being anticipated
by Stone **4880429**. Stone **4,880,429** discloses: a substantially non-immunogenic
prosthetic device for implantation into a vertebrate subject in a region disposed between
and connecting two of the subject's bones, comprising a biocompatible glycosidase-
treated matrix material, wherein the device matrix is adapted to have an in vivo an outer
surface contour substantially the same as that of a region disposed between and
connecting two of the subject's bones; wherein the cross-links having relatively high
density at tip regions of the device and relatively low density at central
regions of the device.; wherein the molecular weight of the molecular
cross-links is within the range of about 800-60,000 Daltons; wherein the cross-links
comprises at least one of the group of glycosaminoglycan molecules consisting of
chondroitin 4-sulfate; chondroitin 6-sulfate; keratin sulfate; dermatan sulfate; and
hyaluronic acid; wherein the matrix material comprises collagen
and glycosaminoglycan cross-links, and (b) wherein the glycosaminoglycan

Art Unit: 3738

cross-links are present at a density less than about 0.95 and greater than about 0.50 cross-link/collagen ratio. See 2:60-67; 3:1-36; 4:35-47; 60-67 ect.

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone **5,108,438**. **5108438** discloses that the device is a prosthetic intervertebral disc, the device being adapted to have an in vivo outer surface contour substantially the same as that of a natural disc; the device matrix being bioresorbable scaffold adapted for ingrowth of vertebral fibrochondrocytes. See 2:59-67; 3:59-67; ect.

Claims 1, 16, 21, 45-46, 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone 6,231,608 6,231,608 discloses these current claims including a device for implantation of a meniscus defect such as tear see 17:40-45; 16:59-67; 17-1-1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 31, 36-38, 44, 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Stone 5,116,374 in view of 6,231, 608. 5,116,374 have been

disclosed above however they do not disclose pore size. 5,116,374 teach the pore sizes as claimed. It would have been obvious to one having skill in the art to utilize various pore sizes in microns in order to control the amount on in-growth tissue surrounding the implant depending upon the location it is to be placed.

Claims 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone 5,116,374 in view 5,007,934 Stone. Stone 5,007,934 teaches a matrix material concentrations dry weights and glycosaminoglycan molecules...see claim 13.

Allowable Subject Matter

Claims 28, 33-35, 39-41, 42, 57-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suzette J Gherbi/
Primary Examiner, Art Unit 3738
10 March 2008